

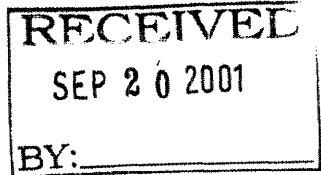
**EMORD & ASSOCIATES, P.C.**

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September 19, 2001



77821

**VIA UPS NEXT DAY AIR**

Dr. Robert Moore - Chief  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street, S.W.  
Washington, DC 20204

***Re: Fulfillment of reporting Obligation  
Under 21 U.S.C. § 343(r) and 21 CFR § 101.93***

Dear Dr. Moore:

Pure Encapsulations, Inc.,<sup>1</sup> in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, hereby submits an original and two copies of its structure/function claim notification within 30 days of first marketing its products with the statements presented below. Pure Encapsulations retains scientific documentation supporting the statements.

**1. Supplement Brand Name**

Pancreatic VegEnzymes

**Supplement Ingredients**

Plant based enzymes derived from aspergillus oryzae, aspergillus niger, and ascorbyl palmitate.

**Text of Statements of Nutritional Support**

These enzymes have several unique properties that enhance their ability to promote the optimal breakdown of foods and nutrients, including broad substrate specificity. Promoting complete digestion.

<sup>1</sup> The address for Pure Encapsulations, Inc. is 490 Boston Post Rd., Sandbury, MA 01776.

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**2. Supplement Brand Name**

Pancreatic VegEnzymes L

**Supplement Ingredients**

Plant based enzymes derived from aspergillus oryzae, aspergillus niger and ascorbyl palmitate.

**Text of Statements of Nutritional Support**

Pancreatic VegEnzymes L consists of protease, amylase, and an enhanced lipase profile for diets high in fat or for specialized digestive support needs.

**3. Supplement Brand Name**

Alpha Lipoic Acid 400 mg

**Supplement Ingredients**

Alpha lipoic acid, ascorbyl palmitate and hypo-allergenic plant fiber.

**Text of Statements of Nutritional Support**

Supports glucose metabolism and nerve health.

**4. Supplement Brand Name**

Soy Isoflavones 40

**Supplement Ingredients**

Soy Isoflavone Extract and hypo-allergenic plant fiber.

**Text of Statements of Nutritional Support**

Genistein supports healthy prostate and breast tissue by maintaining proper cell function and enzyme activity.

Promoting proper estrogen balance and supporting breast health.

In both premenopausal and postmenopausal women, soy isoflavones support healthy lipid metabolism, playing an important role in cardiovascular health.

Furthermore, isoflavone-rich diets have been shown to support bone mineral health in women.

For enhanced cardiovascular support, estrogen metabolism, bone health, and prostate and breast cell health.

**5. Supplement Brand Name**

ChromeMate® GTF 600

**Supplement Ingredients**

Chromium (polynicotinate) and hypo-allergenic plant fiber.

**Text of Statements of Nutritional Support**

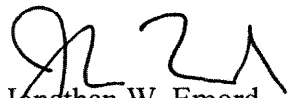
Supports body composition and fat loss in overweight women.

Supports lean muscle mass and fat loss in overweight women.

Maintaining healthy glucose metabolism and weight loss.

In accordance with 21 U.S.C. § 343(r)(6) and 21 CFR § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **“These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”**

Respectfully submitted,



Jonathan W. Emord  
Christopher A. Brown

SEP-19-01 09:27AM FROM-PURE ENCAPSULATIONS

978-443-9664

T-672 P.05/05 F-858

**Certification**

I, Ray Hamel, Manager of Pure Encapsulations, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

Executed on:

9/18/01

Raymond F Hamel  
Ray Hamel